



## **Agricultural Marketing Service**

### **7 CFR Part 66**

**[Doc. No. AMS–FTPP–20–0057]**

**RIN: 0581-AD95**

### **2020 Annual Updates to List of Bioengineered Foods**

**ACTION:** Proposed rule.

**SUMMARY:** The Agricultural Marketing Service (AMS) of the United States Department of Agriculture (USDA) is soliciting comments and feedback on an update to the List of Bioengineered Foods (List) as it pertains to the National Bioengineered Food Disclosure Standard (the Standard or NBFDS).

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** We invite you to submit written comments via the internet at <https://www.regulations.gov>. Comments may also be filed with the Docket Clerk, 1400 Independence Ave. SW, Room 2069-South, Washington, DC 20250; Fax: (202) 260-8369. All comments submitted in response to this notice, including the identity of individuals or entities submitting comments, will be made available to the public on the internet via <https://www.regulations.gov>. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection at: <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Paul Lewis, Director, Food Disclosure and Labeling Division, Fair Trade Practices Program, Agricultural Marketing Service, U.S. Department of Agriculture, Telephone (202) 720-3252, Email: [pauli.lewis@usda.gov](mailto:pauli.lewis@usda.gov).

**SUPPLEMENTARY INFORMATION:**

## **I. Background**

On July 29, 2016, Public Law 114–216 amended the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et. seq.*) (amended Act) to require USDA to establish a national, mandatory standard for disclosing any food that is or may be bioengineered (BE). USDA published a final rule promulgating the regulations (7 CFR Part 66) to implement the Standard on December 21, 2018 (83 FR 65814). The regulations became effective on February 19, 2019, with a mandatory compliance date of January 1, 2022. Under 7 CFR 66.1, a bioengineered food is a food that, subject to certain factors, conditions, and limitations, contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

The regulations, at 7 CFR 66.6, contain the List, which currently includes: alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugarbeet. As stated in the preamble to the final rule, at 83 FR 65852, the List establishes a presumption about what foods might require disclosure under the NBFDS, but does not absolve regulated entities from the requirement to disclose the bioengineered status of food and food ingredients produced with foods not on the List when the regulated entities have actual knowledge that such foods or food ingredients are bioengineered. As a result, if a regulated entity is using a food or ingredient produced from an item on the List, they must make a bioengineered food disclosure unless they have records demonstrating that the food or ingredient they are using is not bioengineered. Similarly, even if a food is not on the List, a regulated entity must make a bioengineered food disclosure if they have actual knowledge that a food or a food ingredient being used is a bioengineered food or a bioengineered food ingredient.

As stated in 7 CFR 66.7(a), AMS will review and consider updates to the List on an annual basis and will solicit recommendations regarding updates to the List through notification in the **Federal Register** and on the AMS website. The regulations further provide that:

(1) Recommendations regarding additions to and subtractions from the List may be submitted to AMS at any time or as part of the annual review process.

(2) Recommendations should be accompanied by data and other information to support the recommended action.

(3) AMS will post public recommendations on its website, along with information about other revisions to the List that the agency may be considering, including input based on consultation with the government agencies responsible for oversight of the products of biotechnology: USDA's Animal and Plant Health Inspection Service (USDA-APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA).

(4) AMS will consider whether foods proposed for inclusion on the List have been authorized for commercial production somewhere in the world, and whether the food is currently in legal commercial production for human food somewhere in the world.

(5) If AMS determines that an update to the List is appropriate following its review of all relevant information provided, AMS will modify the List.

On July 24, 2020, AMS published a Notice in the *Federal Register* seeking public comment on recommendations to update the List (85 FR 44791). In the Notice, AMS sought comments on adding sugarcane (insect-resistant) to the List, and amending "squash (summer)" to "squash (summer, virus-resistant)." As required at 7 CFR 66.7(a)(3), AMS consulted with the government agencies responsible for oversight of the products of biotechnology, APHIS, EPA, and FDA, on this matter.

AMS also sought public comment to determine whether additional information was publicly available regarding bioengineered versions of cowpea and rice. AMS understands that bioengineered versions of cowpea and rice are at various stages of authorization for commercial production but are not yet in legal commercial production for human food. AMS also requested comments on any other foods not mentioned in the Notice that it should consider for addition to the List.

The comment period for the Notice closed on August 24, 2020. AMS received a total of 17 comments. After reviewing the public comments, AMS is proceeding with the proposed rule to add sugarcane (Bt insect-resistant varieties) to the List and amend “squash (summer)” to “squash (summer, mosaic virus-resistant varieties).” AMS did not receive any comments on cowpea or rice and is not proposing any action related to those two crops at this time.

Table 1 summarizes the proposed addition and modification to the List.

**Table 1—Proposed Amendments to the List**

Crop	Regulation	Proposed rule action
Sugarcane	7 CFR 66.6	Add to the List as “Sugarcane (Bt insect-resistant varieties)”
Squash (summer)	7 CFR 66.6	Add additional description to the existing entry on the List to read “squash (summer, mosaic virus-resistant varieties)”

## **II. Overview of Proposed Rule**

### **A. Addition to the List**

AMS received comments that both supported and opposed adding sugarcane (Bt insect-resistant varieties) to the List.

Those in favor of adding sugarcane (Bt insect-resistant varieties) to the List generally agreed that it met the dual criteria identified at 7 CFR 66.7(a)(4) to be added to the List: (1) authorized for commercial production somewhere in the world and (2)

currently in legal commercial production for human food somewhere in the world.

Several commenters also noted that adding sugarcane (insect-resistant) to the List would provide consumers with more information about their food.

Commenters opposed to adding sugarcane (Bt insect-resistant varieties) to the List acknowledged that commercial production of that crop is authorized and taking place in Brazil and that such production is primarily for seedling bulk up, and not for human consumption. However, we have no evidence that seedling bulk up is the only use for the crop, and we believe sugarcane (Bt insect-resistant varieties) could be used for human food and should be included on the List. AMS requests comments with data or evidence that would support or refute the conclusion that seedling bulk up is the only current use for sugarcane (Bt insect-resistant varieties).

Another commenter suggested that sugarcane (insect-resistant) produced in Brazil is unlikely to end up in the United States. Whether a product is likely to end up in the United States is not a factor that AMS must consider under 7 CFR 66.7. The List reflects production of bioengineered foods on a global level and does not consider whether such foods are likely to end up in the United States.

Lastly, some commenters suggested that because sugar produced from sugarcane (insect-resistant) is highly refined and does not contain detectable modified genetic material, it is not a bioengineered food and should not be added to the List. As stated above, the List establishes a presumption about which foods are or may be bioengineered. Inclusion on the List does not affirmatively mean an item on the List, or a food produced from an item on the List, is a bioengineered food. Rather, being on the List establishes a presumption and requires a regulated entity to make a bioengineered food disclosure unless they maintain records, in accordance with 7 CFR 66.9, to demonstrate that modified genetic material is not detectable.

AMS has considered all the information provided to the agency related to sugarcane (insect-resistant) and believes the criteria identified in 7 CFR 66.7(a)(4) are met. Accordingly, this action proposes to update the List to include sugarcane (insect-resistant). AMS invites comments on the proposed addition of insect resistant sugarcane to the List.

## **B. Amendment to the List**

Commenters were generally supportive of adding an additional modifier (virus-resistant) to the existing entry for squash (summer). One commenter noted that the additional modifier increases transparency and provides more information to consumers.

Another commenter asked that AMS consider additional specificity by further amending the entry for squash to include the specific trade name, Performance Series. As mentioned in the preamble to the final rule (83 FR 65819), AMS will, where practical, include specific trade names “to help distinguish bioengineered versions of those foods from their non-bioengineered counterparts.” The List currently includes two foods with specific trade names: Arctic<sup>TM</sup> variety apples and AquAdvantage<sup>®</sup> brand salmon. In each instance, the BE food (Arctic<sup>TM</sup> variety apples or AquAdvantage<sup>®</sup> brand salmon) is the only one of its kind that, to AMS’s knowledge, meets the criteria identified in 7 CFR 66.7(a)(4).<sup>1</sup> However, as explained in the preamble to the final rule, items on the List will necessarily become more generic as more than one variety of a BE food are available (83 FR 65819). Similar to potato, which does not have a specific trade name modifier on the List, there is more than one variety of squash (summer) that meets the criteria

---

<sup>1</sup> Okanagan Specialty Fruits, the producer of Arctic<sup>TM</sup> brand apples, is the only entity to apply for deregulated status for bioengineered apples and to consult with FDA on bioengineered apples. Similarly, AquaBounty Technologies, Inc., the producer of AquAdvantage<sup>®</sup> salmon, is the only entity to gain approval for production of bioengineered salmon. New Plant Variety Consultations, <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=NewPlantVarietyConsultations>. Petition for Determination of Nonregulated Status, <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>. 21 CFR 528.1092; Electronic Animal Drug Product Listing Directory, <https://www.fda.gov/industry/structured-product-labeling-resources/electronic-animal-drug-product-listing-directory>.

identified in 7 CFR 66.7(a)(4).<sup>2</sup> As a result, AMS is not proposing to add a specific trade name to summer squash.

Additionally, adding “virus-resistant” to the existing description would not impact the recordkeeping burden for regulated entities. These entities may still be subject to an examination of customary or reasonable records for summer squash following a BE audit outlined in § 66.402. If regulated entities marketing summer squash or sugarcane are unable to obtain records from suppliers, they can make a disclosure.

After reviewing the public comments, AMS is proceeding with this proposed rule to amend “squash (summer)” to “squash (summer, mosaic virus-resistant varieties).” AMS invites comments on the proposed revision to summer squash on the List to specify “squash (summer, mosaic virus-resistant varieties).

### **III. Required Regulatory Analyses**

#### **A. Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the information collection related to the NBFDS has previously been approved by OMB and assigned OMB No. 0581-0315 – National Bioengineered Food Disclosure Standard. AMS estimates that changes in recordkeeping burden due to the proposed revisions to the List would be minimal.

Generally, the records necessary to substantiate the need for a disclosure /label are customary and reasonable, and therefore maintained in the usual course of business. The same records would be required to substantiate a decision not to label under § 66.9. Limiting reporting to a specific variety of summer squash does not really reduce recordkeeping. These entities may still be subject to an examination of customary or

---

<sup>2</sup> Petitions for Determination of Nonregulated Status, <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status>. New Plant Variety Consultations, <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=NewPlantVarietyConsultations>.

reasonable records for summer squash following a BE audit outlined in § 66.402. It could, however, reduce the burden associated with making disclosures, since fewer labels would be required where summer squash is known not to be bioengineered for virus resistance. Data are not available to measure the change in the number of entities who would be required to comply with the revised disclosure and recordkeeping requirements associated with this proposal, given the seasonal nature of summer squash production and variations in production from year to year. AMS requests comments with data or information on market share or proportion of squash of virus-resistant varieties and the number of entities that might be impacted by this change.

AMS did not receive any substantive comments during the open comment period for the Information Collection renewal request published earlier this year.

## **B. Civil Rights Review**

AMS has considered the potential civil rights implications of this proposed rule on minorities, women, or persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. This review included persons that are employees of the entities that are subject to these regulations.

This proposed rule offers several distinct avenues of compliance for regulated entities that can be tailored to the needs of their consumers. Applying this approach does not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination. AMS's Civil Rights Impact Analysis (CRIA) will be published in the *Federal Register* and on the AMS BE Disclosure webpage along with publication of this proposed rule. A 60-day comment period will be provided to allow interested persons to respond to the CRIA. All written comments received in response to the CRIA and the proposed rule by the date specified will be considered.



### **C. Executive Order 13175**

This rule has been reviewed in accordance with the requirements of Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments.

Executive Order 13175 requires Federal agencies to consult with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or the distribution of power and responsibilities between the Federal Government and Indian tribes.

This proposed rule may impact individual members of Indian tribes that operate as food manufacturers or retailers; however, it would not have a direct effect on tribes or the relationship or distribution of power and responsibilities between the Federal Government and Indian tribes. Therefore, consultation under Executive Order 13175 is not required at this time. However, AMS hosts a quarterly teleconference with Tribal Leaders where matters of mutual interest regarding the marketing of agricultural products are discussed. During two quarterly teleconference calls on March 11, 2021, and July 22, 2021, AMS provided Tribal representatives with an overview of the upcoming proposed rule that would add “sugarcane (insect-resistant)” to the List and amend “squash (summer)” to “squash (summer, mosaic virus-resistant varieties),” and extended the opportunity for questions and requests for additional information. At that time, AMS received no questions or requests from Tribal representatives. AMS will continue to extend outreach to ensure tribe members are aware of the requirements and benefits under this proposed rule once final. Where Tribes request consultation on relevant matters that are not required under legislation, AMS will collaborate with the Office of Tribal Relations.

### **D. Executive Orders 12866 and 13563**

USDA is issuing this proposed rule in conformance with Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, which include potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Pursuant to 7 CFR 66.7(b), “[r]egulated entities will have 18 months following the effective date of the updated List of Bioengineered Foods to revise food labels to reflect changes to the List in accordance with the disclosure requirements of this part.” As this rule has been designated “Significant,” it has been reviewed by the Office of Management and Budget.

Cost changes due to this action will be limited to the addition of sugarcane to the List because regulated entities have already incurred costs associated with the inclusion of summer squash on the List. The addition of sugarcane to the List would not increase the cost of federal enforcement. To estimate the cost of the proposed action, the Label Insight Database was used to determine the number of products that use cane sugar as an ingredient and which have no other ingredients that would otherwise require labeling of the product as bioengineered as described in the regulatory impact analysis for the final rule on page 19.<sup>3</sup> A total of 10,600 individual UPCs were identified using this criteria. The upper and lower bounds of the estimate were calculated by multiplying 10,600 UPC by the unit cost for testing (unit cost range: \$153-\$431) and for analytical costs (unit cost range: \$376-\$3,084) established in the 2018 Final Rule. AMS estimates that the costs associated with this action would range from \$6 million to \$37 million for the initial year, with no ongoing annual costs and no significant change in benefits. Most of the estimated costs are related to a one-time deliberation by food manufacturers to confirm

---

<sup>3</sup> <https://www.regulations.gov/document/AMS-TM-17-0050-14035>

the source of sugar used in their products and to comply with recordkeeping and labeling requirements. If regulated entities marketing summer squash or sugarcane are unable to obtain records from suppliers, they can make a disclosure.

The annualized cost of adding sugarcane to the list of potentially bioengineered products would be between \$500,000 and \$3.5 million (annualized over 20 years using a seven percent discount rate). The rule is, therefore, not considered to be economically significant under Executive Order 12866. Even considering only the first year (where all of the costs are expected to occur), the estimated costs do not exceed the \$100 million threshold for economically significant.

#### **E. Initial Regulatory Flexibility Analysis**

AMS has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities, consistent with statutory objectives. AMS has concluded that the proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities.

The proposed addition of sugarcane (insect-resistant) and proposed amendment of “squash (summer)” to “squash (summer, mosaic virus-resistant varieties)” to the List would directly affect three industry sectors: cane sugar manufacturers, processed food manufacturers who use cane sugar or summer squash as ingredients, and grocery or other retailers who sell raw sugarcane (insect-resistant) or summer squash.

According to the 2017 Study of U.S. Business (SUSB) from the US Census, there were 37 cane sugar manufacturers in the United States. Approximately 32 of the total cane sugar manufacturers would meet the Small Business Administration definition of small. Of the 32 small firms, 11 would also qualify as very small manufacturers under

the NBFDS regulations and would be exempt from disclosure requirements.

Accordingly, those 11 firms would incur no costs associated with the addition of sugarcane (insect-resistant) to the List of Bioengineered Foods. The remaining 21 small firms would not likely face significant costs as they only have one product and are likely to know where the cane for their sugar originates. At this time sugarcane (insect-resistant) is grown commercially only in Brazil. If sugarcane (insect-resistant) becomes more prevalent, cane sugar producers could potentially be required to keep records on the origin of the cane processed into sugar and could incur certification costs associated with demonstrating that the final product has no detectable rDNA. Assuming that the refinement of cane sugar, like beet sugar, would support such a certification, cane sugar producers would face minimal labeling costs.

Food manufacturers who only use cane sugar as an ingredient will need to determine the certification status of the sugar they use – assuming sugar made from sugarcane (insect-resistant) makes it into the U.S. market. Most food manufacturers will already face costs associated with confirming the ingredients of their products and the marginal cost associated with an additional ingredient is expected to be small. As with beet sugar, it is unlikely that refined cane sugar would contain traceable levels of rDNA. As a result, regulated entities may not have additional labeling costs due to the addition of sugarcane (insect-resistant) to the List as there is a means to exempt their products from disclosure.

Food manufacturers whose products contain summer squash and retailers who sell uncooked summer squash will see no change or, potentially, a slight reduction in costs as the proposal would reduce the varieties of squash that require labeling. Food manufacturers whose products contain summer squash and retailers who sell uncooked summer squash are already maintaining records in accordance with the NBFDS.

Food manufacturers who use summer squash are likely concentrated in Fruit and Vegetable Preserving and Specialty Food Manufacturing (NAICS 3114). This industry sector had 1,540 firms listed in the 2017 SUSB. Of these, approximately 1,475 would be classified as small. An additional 904 firms would be classified as very small by the NBFDS rule and, therefore, be exempt. Food manufacturers already face the administrative costs associated with using a product on the List of Bioengineered Foods. The proposal would make it easier for regulated entities, who are already maintaining records in compliance with the NBFDS, to demonstrate that labeling is not required if they know they are not receiving virus-resistant varieties. The proposal could also result in a slight decrease in the cost of labeling products containing summer squash if it is possible and desirable to avoid virus-resistant varieties. However, we do not attempt to quantify this reduction in any way. Costs to small food producers using summer squash therefore will remain unchanged or be reduced by this proposal.

Similarly, retailers will be primarily affected by the change in the definition of summer squash. Their costs will remain the same as they are now or be reduced slightly if they do not need to label as many products.

For these reasons, AMS is certifying that the proposal to add sugarcane (Bt insect-resistant varieties) to the List of Bioengineered Foods and limiting the varieties of squash listed as bioengineered foods to virus-resistant varieties will not have a significant economic impact on a substantial number of small entities.

#### **F. Executive Order 12988**

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. The proposed rule is not intended to have retroactive effect. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

#### **List of Subjects**

## **7 CFR Part 66**

Agricultural commodities, Food labeling, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Agricultural Marketing Service proposes to amend 7 CFR part 66 as follows:

### **PART 66—NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD**

1. The authority citation for 7 CFR part 66 continues to read as follows:

**Authority:** 7 U.S.C. 1621 *et seq.*

2. Revise § 66.6 to read as follows:

#### **§ 66.6 List of Bioengineered Foods.**

The List of Bioengineered Foods consists of the following: Alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer, mosaic virus-resistant varieties), sugarbeet, and sugarcane (Bt insect-resistant varieties).

**Erin Morris,**

*Associate Administrator,*

*Agricultural Marketing Service.*

[FR Doc. 2022-15728 Filed: 7/21/2022 8:45 am; Publication Date: 7/22/2022]